REMARKS

FORMAL MATTERS:

Claims 1-22 are pending after entry of the amendments set forth herein.

The specification is amended to provide the abstract as a single paragraph. Support for the amendment is found in the abstract as originally filed.

Claims 1 and 11 are amended. Support for these amendments is found, for example, in the specification at page 2, 3rd full paragraph; and page 7, 1st full paragraph.

New claims 15-22 are added. Support for these new claims is found throughout the specification and in, for example, claims 1-10 as originally filed.

No new matter is added.

INFORMATION DISCLOSURE STATEMENT:

Applicant notes that an Information Disclosure Statement (IDS), including an SB/08A form, was submitted in this application on July 13, 2004. Applicant respectfully requests that the Examiner initial and return this SB/08A form, thereby indicating that the references cited in the IDS have been reviewed and made of record. For the Examiners convenience, a copy of this form is enclosed herewith.

ABSTRACT

The abstract was objected to as not being limited to a single paragraph. The abstract has been amended accordingly.

Withdrawal of this objection is respectfully requested.

ALLOWABLE SUBJECT MATTER

Applicant is grateful to the Examiner for indicating that claims 3-4, while objected to as being dependent upon a rejected base claim, would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims.

OBJECTIONS TO THE CLAIMS

Claim 11 was objected on the grounds the claim does not recite a patient or subject to whom the compound is administered. The amendment to claim 11 addresses this objection. Withdrawal of the objection is respectfully requested.

REJECTIONS UNDER §112, ¶2 AND §101

Claims 13 and 14 were rejected as being indefinite (§112, ¶2) and for improper definition of a process. In view of the cancellation of these claims, this rejection is rendered moot.

REJECTIONS UNDER §102

Claims 1-2, and 5-14 were variously rejected under §102 as set out below.

Rejection under §102(a) or §102(b) – Jin et al.

Claims 1-2, 5 and 9-14 were rejected as being anticipated by the Jin et al. abstract ("Jin et al.").[1]

This rejection is respectfully traversed as applied and as it may be applied to the amended claims.

None of the claims are anticipated by Jin et al. Applicant notes that the HeLa cells referred to in Jin et al. are a cell line derived from an adenocarcinoma of cervix epithelium (see ATCC product description, attached as Exhibit A). HeLa cells are not leukemia cells or melanoma cells.

Jin et al. does not disclose or suggest a composition that induces apoptosis in leukemia or melanoma, and thus does not describe an "anti-leukemia" or an "anti-melanoma" composition as recited in the present claims. Jin et al. does not disclose or suggest a method for treatment of melanoma or leukemia.

The apoptosis-inducing effects of the claimed compositions and their use in the claimed methods in treating leukemia or melanoma is not described in Jin et al. Moreover, the apoptosis-inducing effects of the claimed compositions and their use in the claimed methods in treating leukemia or melanoma would also not be obvious over Jin et al. One can not extrapolate the results of Jin et al. in HeLa cells to the anti-leukemia and anti-melanoma effects discovered by the present inventor. The ordinarily skilled

artisan could not have predicted the anti-leukemia or anti-melanoma effect of the compositions without actually carrying out the research for these tumors, as the inventor has done here.

Withdrawal of this rejection is respectfully requested.

Rejection under §102(b) – Janusz et al. (J. Med. Chem 1993 36:2595-2604) or Janusz et al. (U.S. Pat. No. 4,898,887)

Claims 1-2, 5-6, 7-8, and 13-14 as being anticipated by Janusz et al. (1993 J. Med. Chem 36:2595-2604) or Janusz et al. (U.S. Pat. No. 4,898,887) (referred to here a "Janusz et al. (journal)" and "Janusz et al. (US'887)", respectively, and collectively as "the Janusz et al. references"). This rejection is respectfully traversed as applied and as it may be applied to the amended claims.

The Janusz et al. references, at best disclose anti-nociceptive and anti-inflammatory compositions. Neither of the Janusz et al. references discloses or suggests a composition that induces apoptosis in leukemia or melanoma, and thus does not describe an "anti-leukemia" or an "anti-melanoma" composition as recited in the present claims. Neither of the Janusz et al. references discloses or suggests a method for treatment of melanoma or leukemia.

The apoptosis-inducing effects of the claimed is not described in the Janusz et al. references. Moreover, the apoptosis-inducing effects of the claimed compositions and their use in the claimed methods in treating leukemia or melanoma would also not be obvious over Janusz et la. One can not predict such an anti-leukemia or an anti-melanoma effect by extrapolation from an anti-nocicpetive or anti-inflammatory effect. Such anti-leukemia or an anti-melanoma effects could not have been predicted without actually carrying out the research for these tumors, as the inventor has done here.

Withdrawal of this rejection is respectfully requested.

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[1] The abstract cited is from the Japanese publication Jin et al. 2002 "Effect of capsaicin and N-docosahexaenoly-vanillylamide on growth of taxol-tolerant HeLa cells" Nippon Shokuhin Kagaku Gakkaishi 9(2):50-53.

Rejection under §102(e) – Martin et al.

Claims 1-2, 5-6, and 13-14 were rejected as being anticipated by Martin et al., US 2004/0122089 ("Martin et al."). This rejection is respectfully traversed as applied and as it may be applied to the amended claims.

Applicant notes that Martin et al., cited as art under §102(e), has a filing date of February 13, 2003, and claims priority a continuation-in-part of application serial no. 10/170,204, filed June 13, 2002. Applicant's Japanese priority date is December 5, 2002, which date is intervening. Thus if the disclosure relied upon in the published application of Martin et al. is not present in the priority application, then Martin et al. would be not available as prior art against the present claims.

Martin et al. does not disclose or suggest a composition that induces apoptosis in leukemia or melanoma, and thus does not describe an "anti-leukemia" or an "anti-melanoma" composition as recited in the present claims. Martin et al. does not disclose or suggest a method for treatment of melanoma or leukemia.

Martin et al. at best discloses that arvanil has an anti-proliferative effect on human breast cancer cells, and further discloses analgesic compositions. The apoptosis-inducing effects of the claimed compositions and their use in the claimed methods in treating leukemia or melanoma is not described in Martin et al. Moreover, the apoptosis-inducing effects of the claimed compositions and their use in the claimed methods in treating leukemia or melanoma would also not be obvious over Martin et al. One can not extrapolate from the disclosure in Martin et al. relating to anti-breast cancer cell activity or analgesic activity to the anti-leukemia and anti-melanoma effects discovered by the present inventor. The ordinarily skilled artisan could not have predicted the anti-leukemia or anti-melanoma effect of the compositions without actually carrying out the research for these tumors, as the inventor has done here.

Withdrawal of this rejection is respectfully requested.

Rejection under §102(b) – Chen

Claims 1-2, 5-7, and 13-14 were rejected as being anticipated by Chen U.S. Pat. No. 5,221,692. ("Chen"). This rejection is respectfully traversed as applied and as it may be applied to the amended claims.

Chen does not disclose or suggest a composition that induces apoptosis in leukemia or melanoma, and thus does not describe an "anti-leukemia" or an "anti-melanoma" composition as recited

in the present claims. Chen does not disclose or suggest a method for treatment of melanoma or leukemia.

Chen at best discloses that olvanil has activity as an anti-inflammatory analgesic agent. The apoptosis-inducing effects of the claimed compositions and their use in the claimed methods in treating leukemia or melanoma is not described in Chen. Moreover, the apoptosis-inducing effects of the claimed compositions and their use in the claimed methods in treating leukemia or melanoma would also not be obvious over Chen. One can not extrapolate from the disclosure in Chen relating to analgesic activity to the anti-leukemia and anti-melanoma effects discovered by the present inventor. The ordinarily skilled artisan could not have predicted the anti-leukemia or anti-melanoma effect of the compositions without actually carrying out the research for these tumors, as the inventor has done here.

Withdrawal of this rejection is respectfully requested.

Rejection under §102(a) or §102(b) – Takahata et al.

Claims 1-2, 5, 9-10 and 13-14 were rejected as being anticipated by the Takahata et al. abstract.[2] This rejection is respectfully traversed as applied and as it may be applied to the amended claims.

A complete copy of Takahata et al. is provided in Exhibit B, with the publication date of October 1, 2002 translated on page 64 of the reference. The October 1, 2002 publication date of Takahata et al. is less than one year before the instant application's U.S. filing date of August 4, 2003. Therefore, Takahata et al. is not available as prior art under §102(b).

Takahata et al. is also not available as art under §102(a), since this reference is not "by another".

As set forth by the court in *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982), and as further discussed at MPEP §715.01(c) and §2131.01, authorship of an article by itself does not raise a presumption of inventorship with respect to the subject matter disclosed in the article. Thus, coauthors may not be presumed to be co-inventors merely from the fact of co-authorship. Where the applicant is one of the co-authors of a publication cited against his application, the publication may be removed as a reference by submission of a specific declaration by the applicant establishing that the article is describing applicant's own work. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

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[2] The abstract cited is from the Japanese publication Takahata et al. 2002 "Induction of cancer cell apoptosis by docosahexaenoic acid (DHA) derivative Dohevanil of a spicy component capsaicin" New Food Industry 44(10):6-12.

As set out in the Declaration of Kyoyo Takahata Under 37 C.F.R. §1.132 filed with this amendment,[3] the Takahata et al. reference describes the inventor's own work, and is thus not a publication by another. As stated in Dr. Takahata's declaration, the other co-authors -- Kimie Ishihata and Eifuku Kim-- are not inventors of the claimed invention, but were named as co-authors due to technical contributions they provided. Neither Ishihata nor Kim contributed inventive input with respect to the invention disclosed and claimed in this application.

Withdrawal of this rejection is respectfully requested.

REJECTIONS UNDER §103(A)

Rejection under §103(a) – Martin et al.

Claim 11 was rejected as being unpatentable over Martin et al. This rejection is respectfully traversed as applied and as it may be applied to the amended claims.

As set out in MPEP §2143, three basic criteria must be met to establish a prima facie case of obviousness: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art reference, or references when combined, must teach or suggest all the claim limitations. All three criteria must be met. If any one of these three criteria is not met, a prima facie case of obviousness has not been established.

As discussed above, Martin et al. does not disclose or suggest method for treatment of melanoma or leukemia using the composition recited in claim 11. Martin et al. at best discloses that arvanil has an anti-proliferative effect on human breast cancer cells, and discloses analgesic compositions. The apoptosis-inducing effects of the claimed compositions, and their use in the claimed methods in treating leukemia or melanoma, is simply not suggested by the disclosure of Martin et al.

In addition, Martin et al. would not provide the ordinarily skilled artisan the requisite reasonable expectation of success. One can not extrapolate from the disclosure in Martin et al. relating to anti-breast cancer cell activity or analgesic activity to the anti-leukemia and anti-melanoma effects discovered by the present inventor. The ordinarily skilled artisan could not have predicted the anti-leukemia or anti-

[3] An executed version of Dr. Takahata's declaration will be filed in a supplemental communication.

melanoma effect of the compositions without actually carrying out the research for these tumors, as the inventor has done here. Therefore, the prima facie case of obviousness can not stand.

Withdrawal of this rejection is respectfully requested.

Rejection under §103(a) – Takahata et al.

Claims 11-12 were rejected as being unpatentable over Takahata et al.. This rejection is respectfully traversed as applied and as it may be applied to the amended claims.

As discussed above, Takahata et al. is not available as a reference under either §102(b) or §102(a).

As set out in MPEP §2141.01, a reference must be available as prior art under §102 in order to be the basis for a rejection under §103. Because Takahata et al. is not available as prior art under §102, Takahata et al. is also not available as prior art under §103.

Withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number ORIN-004.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: April 6, 2005

By: _____
Carol L. Francis
Registration No. 36,513

Enclosure(s): Copy of Information Disclosure Statement (IDS) filed July 13, 2004
Exhibit A: ATCC Product Description for HeLa Cells
Exhibit B: Takahata et al. 2002 "Induction of cancer cell apoptosis by docosahexaenoic acid (DHA) derivative Dohevanil of a spicy component capsaicin" New Food Industry 44(10):6-12. (translation of publication date provided on page 64)
Declaration of Kyoyo Takahata Under 37 C.FR. §1.132 (unexecuted)

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